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ONO PHARMACEUTICAL CO., LTD.
Corporate Communications
public_relations@ono.co.jp

Helsinn Group, Switzerland, announced the results of
Phase III Trials (ROMANA 1 and ROMANA 2) of Anamorelin/ONO-7643
in patients with Cancer Anorexia-Cachexia Syndrome (CACS)
associated with Non-Small Cell Lung Cancer

Helsinn Group ("Helsinn") announced on September 27, 2014 (Switzerland local time) that anamorelin/ONO-7643, a ghrelin receptor agonist, significantly increased lean body mass, body weight and improved symptoms compared to placebo in the Phase III trials (ROMANA 1 and ROMANA 2) in patients with cancer anorexia/cachexia syndrome (CACS) associated with non-small cell lung cancer.

In accordance with the license agreement entered into October 2006, Ono has exclusive rights to develop and commercialize anamorelin/ONO-7643 in Japan, South Korea and Taiwan, and is currently conducting a Phase II trial in patients with cancer cachexia associated with non-small cell lung cancer.

Attached is the press release distributed by Helsinn for your information.

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Pivotal Phase III Trial Data for Anamorelin in ROMANA 1 and 2 Studies in Non-Small Cell Lung Cancer Patients with Anorexia-Cachexia Shows Significant Increase in Lean Body Mass, Body Weight and Improved Symptoms

Lugano, Switzerland, Sept 27th, 2014—The Helsinn Group, a Company focused on building quality cancer care, announces that anamorelin, its novel, once-daily ghrelin receptor agonist significantly increased lean body mass (LBM) compared with placebo in two Phase III trials comprising the largest trial program of its kind to date in non-small cell lung cancer (NSCLC) patients with cachexia, an area of significant unmet medical need
In both pivotal 12-week studies, ROMANA 1 and ROMANA 2, anamorelin was shown to significantly increase lean body mass ($p<0.0001$) compared with placebo, and was generally well tolerated; serious drug-related adverse events affected less than 3% of patients, mainly relating to hyperglycemia and diabetes.

Compared with placebo, anamorelin consistently increased body weight ($p<0.0001$), and improved patient symptoms and concerns ($p=0.0004$ and $p=0.0016$) related to Cancer Anorexia-Cachexia, as secondary endpoints in both studies. Changes in hand-grip strength, the second primary endpoint investigated, were not significantly different from placebo in either the ROMANA 1 or ROMANA 2 studies.

Jennifer Temel, MD, Clinical Director of Thoracic Oncology at Massachusetts General Hospital Cancer Center and a Principal Investigator in the ROMANA 1 and ROMANA 2 trials, commented: “These data show that anamorelin represents a new option in the treatment of anorexia-cachexia syndrome in patients with advanced non-small cell lung cancer in which patients frequently experience poor QOL due to symptoms such as cachexia, loss of appetite and fatigue. The ROMANA data clearly demonstrates that anamorelin increased lean body mass and improved symptoms related to anorexia and cachexia.”

Riccardo Braglia, Helsinn Group CEO said: “Anamorelin may significantly alleviate some of the most significant symptoms of Cancer Anorexia-Cachexia for patients with non-small

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cell lung cancer, among the most important factors in preserving the best possible quality of life for patients with this disease."

"Anamorelin offers the potential for a new approach to treating the symptoms of this multifactorial clinical condition, which can be devastating for patients and caregivers, for whom getting the most out of every day is crucial."

Methodology

ROMANA 1 and ROMANA 2 were two international, 12-week, double-blind, Phase III trials evaluating the efficacy and safety of anamorelin in patients with unresectable Stage III/IV NSCLC with an ECOG performance score (measuring the performance and health of patients) of 0-2 and cachexia (≥5% weight loss within six months or BMI <20 kg/m^2). Patients were randomized (2:1) to 100 mg anamorelin or placebo, given daily orally for 12 weeks and were permitted to receive chemotherapy while on study. Co-primary endpoints were change from baseline over 12 weeks in lean body mass (measured by Dual-energy X-ray absorptiometry) and in handgrip strength. Secondary endpoints included change in body weight and in the anorexia-cachexia subdomain of the Functional Assessment of Anorexia/Cachexia Therapy (FAACT) questionnaire). Safety assessments included lab values and adverse events.

Results

Over 12 weeks, anamorelin significantly increased LBM compared with placebo ($p<0.0001$) in both studies. In ROMANA 1, the median change in LBM was 1.10 kg [95% CI 0.76; 1.42] for anamorelin compared with -0.44 kg [95% CI -0.88; 0.20] for placebo. In ROMANA 2, the median change in LBM was 0.75 kg (95% CI 0.51; 1.00) for anamorelin compared with -0.96 kg (95% CI -1.27; -0.46) for placebo. Change in handgrip strength was not statistically different between study arms. Anamorelin (vs placebo) increased body weight (2.20±0.3 vs 0.14±0.4 kg; $p<0.0001$; and 0.95±0.4 vs -0.57±0.4 kg; $p<0.0001$) and improved Functional Assessment of Anorexia-Cachexia Treatment (FAACT) subdomain scores (4.12±0.8 vs 1.92±0.8; $p=0.0004$; and 3.48±0.9 vs 1.34±1.0; $p=0.0016$).

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Notes for editors:

About Cancer-anorexia-cachexia syndrome

Cancer anorexia-cachexia syndrome (CACS), characterized by decreased body weight, mainly lean body mass (LBM), is a common, poorly-understood and debilitating condition in patients with cancer, that frequently occurs in patients with advanced NSCLC, for which existing treatment approaches are limited.

NSCLC

Non-small cell lung cancer accounts for roughly 85% of all lung cancer cases. Lung cancer, which has some of the poorest survival rates of any cancers, is the most common form of cancer globally.

About anamorelin and ghrelin

Anamorelin HCl is an investigational selective, novel, orally active ghrelin receptor agonist that is under evaluation for the treatment of Cancer Anorexia-Cachexia in NSCLC patients. Ghrelin is an endogenous peptide secreted by the stomach. Upon binding to its receptor, ghrelin stimulates multiple pathways in the positive regulation of body weight, lean body mass, appetite and metabolism.

About the Helsinn Group

Helsinn is a family run, privately owned pharmaceutical group focused on building quality cancer care with a large portfolio of products. Founded in 1976 with headquarters in Lugano, Switzerland, Helsinn also has operating subsidiaries in Ireland, the USA and a representative office in China. Helsinn's business model is focused on the licensing of pharmaceuticals, medical devices and nutritional supplement products in the therapeutic area of cancer care.

Helsinn Group in-licenses early-to-late stage new chemical entities, completing their development by performing pre-clinical/clinical studies as well as associated manufacturing activities. Helsinn then prepares necessary regulatory filings in order to achieve marketing approvals worldwide. Helsinn's products are out-licensed to its global network of marketing and commercial partners that have been selected for their local market knowledge. Helsinn supports these partners by providing a full range of product and scientific management services, including commercial, regulatory, and medical marketing advice. Helsinn has built a large product portfolio of cancer care products with the alliance of over 65 global partners.

In March 2013, Helsinn established a new commercial organization within its subsidiary, Helsinn Therapeutics (U.S.), Inc., in order to conduct direct sales and marketing activities within the U.S. market. Helsinn's products are manufactured according to the highest quality, safety, and environmental standards at Helsinn's GMP facilities in Switzerland and Ireland from where they are then supplied worldwide to customers.

Further information on Helsinn Group is available at www.helsinn.com

For more information, please contact:

Helsinn Group

Paola Bonvicini

Head of Communication & Press Office

Tel: +41 91-985-21-21

info-hhc@helsinn.com

For media / external inquiries

Consilium Strategic Communications

Mary-Jane Elliott / Jessica Hodgson / Matthew Neal / Laura Thornton

Tel: +44 (0)203 709 5700

Helsinn@consilium-comms.com